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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,819	03/18/2004	Rae Ellen Syverson	KCC 4749.1 (K-C 16,858.1)	7018

321 7590 07/25/2007

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
07/25/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/803,819	SYVERSON ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *5,12,13 and 26-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-11 and 14-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

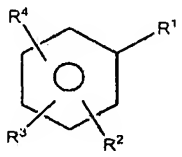
Claims 1-60 are pending. Claims 5, 12, 13 and 26-60 have been pending.

Upon careful consideration, the finality of the office action dated 11-30-06 has been withdrawn. Instant claims 1-4, 6-11 and 14-25 have been rejected in view of the following new rejection:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al. (J. Clin. Microbiol. 1987) and Lambert (J Applied Microbiol.) in view of US 6,416,779 to D' Augustine et al OR D'Augustine et al in view of Robbins et al and Lambert.

> 1. (original) An exoprotein inhibitor for inhibiting the production of exoproteins from Gram positive bacteria in and around the vagina comprising a non-absorbent substrate for insertion into a vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche, the non-absorbent substrate having deposited thereon an effective amount of a first active ingredient having the general formula:
>
> 
>
>
> wherein R^1 is $-OR^6OH$; R^6 is a divalent saturated or unsaturated

Robbins et al studied the production of toxic shock syndrome toxin 1 by Staphylococcus aureus (S. aureus) as determined by tampon-disk-membrane- agar method. Robbins et al teach that the occurrence of toxic shock syndrome due to infection or colonization of S. aureus and its association with the use of tampons in menstruating women (page 1446, col. 1). Robbins et al observed that tampons of different materials supported characteristic levels of growth and toxin production by S. aureus (table 1, page 1447 and results on page 1448, col. 1). Robbins et al conclude that the tampons provide a fibrous surface for heavy colonization by S. aureus and also observed a decrease in toxic shock syndrome toxin (TSST) production by inhibiting the growth of S. aureus by additives such as surfactants (last column on page 1449).

Robbins fails to teach the first active ingredient of the instant claims.

Lambert studied the minimum inhibitory concentrations of different antimicrobial compounds against S. aureus and observed that phenoxyethanol and phenyl ethyl alcohol (designated as PoE and PeA respectively) are effective against S. aureus (abstract, page 276, col. 1, table 2, page 278, col. 2 and Discussion), even though the MICs vary with the inoculum levels. Lambert does not teach phenoxyethanol on anon-absorbent article as claimed in the instant invention.

D'Augustine teaches a method for treating intravaginal or transvaginal bacterial, fungal, viral or parasitic infections comprising a device that contains a pharmaceutically effective amount of an antimicrobial, antifungal, antiviral or antiparasitic agent. D'Augustine teaches the device in the form of a non-absorbent tampon or tampon-like

device, intravaginal sponge or ring etc (col. 2, summary of invention, col. 3 & col. 7, lines 1-29, brief description of figure 15).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ antibacterial compound, phenoxyethanol of Lambert on the non-absorbent feminine devices such as tampons, intravaginal sponge etc., described by D'Augustine for inhibiting the production of exotoxin 1 and treating toxic shock syndrome (TSS) in women using tampons because Robbins et al teaches inhibition of toxin production as well as inhibiting the growth of S. aureus by adding additives or compounds on the tampons and Lambert suggests phenoxyethanol as effective against S. aureus. With respect to the claimed amounts of Lambert teaches the minimum inhibitory concentrations for phenoxyethanol and accordingly, optimizing the amounts of the same so as to achieve the inhibition of S. aureus would have been within the scope of a skilled artisan. However, generally the differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

2. Claims 1-4, 6-11 and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al. (J. Clin. Microbiol. 1987) and Lambert (J Applied

Microbiol.) in view US 5,612,045 to Syverson or Syverson in view of Robbins et al and Lambert.

The teachings of Robbins et al and Lambert have been discussed above.

Syverson teaches absorbent articles and non-absorbent articles such as catamenial tampons for absorbing body fluids that include an effective amount of a compound that substantially inhibit the production of exoprotein produced by Gram positive bacteria, particularly produced by S. Aureus (abstract, col. 3, lines 40-60). The compounds of Syverson comprise ethers, which are the same as the elected sub-species of the instant claims (col. 3, lines 61-55). Syverson teaches including effective amounts of ether compounds and combinations of other antimicrobial or antibacterial compounds (col. 5).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the antibacterial phenoxyethanol of Lambert, which is effective against S. aureus, together with ether compounds in the articles of Syverson because Robbins et al teach S. aureus causes toxic shock syndrome in women using tampons and Syverson suggests employing compounds that for inhibiting toxic shock syndrome (caused by S. aureus) on devices such as tampons. Alternatively, Syverson does not teach the claimed first active agent. However, it would have been obvious for one of an ordinary skill in the art at time of the instant invention to incorporate phenoxyethanol of Lambert in the article of Syverson because Lambert teaches phenoxyethanol is effective against S. aureus and Robbins teaches inhibition of S. aureus toxin production by adding the inhibitors on tampons. In this regard, Robbins et al show that the toxin

production does not depend on the type of article (tampon) used. Further, optimizing the amounts of ether (of Syverson) and phenoxyethanol of Lambert, with an expectation to provide the optimum inhibitory effect of S. aureus toxin production would have been within the scope of a skilled artisan.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4, 6-11 and 14-25 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 10-11, 16-31, 34-46 and 48-51 of copending Application No. 09/969,299 in view of Robbins et al. Co-pending applications claims a catamenial tampon comprising an absorbent material, a first active agent and second active agent (dependent claims).

The first and second active agents (phenoxyethanol and ether respectively) of the instant claims are also recited in the co-pending claims. The active agents of the co-pending claims are employed for the same purpose i.e., inhibiting the production of toxin by S. aureus. Instant claims differ from the co-pending claims in the type of article claimed. Instant claims recite a non-absorbent article as opposed to an absorbent article of the copending claims.

Robbins et al studied the production of toxic shock syndrome toxin 1 by Staphylococcus aureus (S. aureus) as determined by tampon-disk-membrane- agar method. Robbins et al teach that the occurrence of toxic shock syndrome due to infection or colonization of S. aureus and its association with the use of tampons in menstruating women (page 1446, col. 1). Robbins et al observed that tampons of different materials supported characteristic levels of growth and toxin production by S. aureus (table 1, page 1447 and results on page 1448, col. 1). Robbins et al conclude that the tampons provide a fibrous surface for heavy colonization by S. aureus and also observed a decrease in toxic shock syndrome toxin (TSST) production by inhibiting the growth of S. aureus by additives such as surfactants (last column on page 1449). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ any type of tampon, absorbent or non-absorbent, for incorporating the active agents of the co-pending claims because Robbins et al suggests that the irrespective of the type or brand used, all of the tampons provide the required fibrous surface for the growth of S- aureus and that the growth and the toxin production by S. aureus can be inhibited by adding additives to the surface of tampons. Thus, a skilled

artisan would have expected to inhibit the toxin production with the active agents of the co-pending any type of (absorbent or non-absorbent) articles.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
July 18, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600